MAY 1 5 2001

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is: K010565.

The device name is the Dynatron STS. The common or usual name and classification name is: Interferential Current Therapy Device (84LIH). Interferential Current Therapy has not been formally classified. However, based on previous applications , it has been treated as a Class II device. The equivalent or predicate device is the Dynatron 650 (K950348).

The Dynatron STS is an interferential current therapy device that provides eight-channels of output through two treatment ports. The device allows for the selection of multiple presets, adjustment of treatment time, adjustment of treatment intensity and certain custom features that allow for setting frequency, doing lead testing and other functions similar to the predicate device. The device utilizes FDA compliant patient leads per 21 CFR Part 898 and the IEC 601 Medical Device Standard. The hardware and software design is a subset of the Dynatron 650.

The device is intended for the "symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain".

The Dynatron STS provides output wave-forms consistent with interferential current therapy of the Dynatron 650 predicate device.

This device is designed to comply with all requirements for UL544 (and corresponding IEC 601, and Canadian Standards Association regulations).

John S. Ramey

February 23, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2001

Mr. John S. Ramey
Regulatory Affairs
Dynatronics Corporation
7030 Park Centre Drive
Salt Lake City, Utah 84121

Re: K010565 and K010948
Trade Name: Dynatron STS and Dynatron STS RX
Regulatory Class: Unclassified
Product Code: LIH
Dated: February 23 and March 27, 2001
Received: February 26 and March 29, 2001

Dear Mr. Ramey:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting the devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning the devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing the devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices result in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K010565

Device Name: Dynatron STS (Interferential Current Therapy Device)

Indications For Use:

Interferential therapy delivered by the Dynatron STS is indicated for the following uses:

"symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain".

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010565